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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/569,714	09/21/2006	Elisabeth Meyer	930008-2207	5929
7590 Ronald R Santucci Frommer Lawrence & Haug 745 Fifth Avenue New York, NY 10151			EXAMINER CHEN, CATHERYNE	
			ART UNIT 1655	PAPER NUMBER
			MAIL DATE 02/07/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/569,714	<b>Applicant(s)</b> MEYER ET AL.	
	<b>Examiner</b> Catheryne Chen	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 7, 9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8 and 11-22 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>Feb. 24, 2006</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Currently, Claims 1-22 are pending. Claims 1-6, 8, 11-22 are examined on the merits. The Office action of Non-responsive mailed on Jan. 9, 2008 is vacated.

### ***Election/Restrictions***

Claims 7, 9-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on Nov. 16, 2007.

Applicant's election with traverse of the species matrix type patch, synthetic rubber, styrene-butadiene-styrene-block-copolymer, polybutylacrylate, N-methyl-pyrrolidone, organic acids, polyester in the reply filed on Nov. 16, 2007 is acknowledged. The traversal is on the ground(s) that there is no lack of unity between the species. This is not found persuasive because under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: For Claim 3, the different types of patches are structurally distinct. For Claims 6, 8, 10, 18-20, the chemicals are structurally distinct. A search of one group is not coextensive with the search of the other groups. Thus, it would be burdensome to search the entire claims.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Objections***

Claim 8 is objected to because they all depend from non-elected Claim 7. If Claim 7 were cancelled, a rejection under 35 U.S.C. 112, second paragraph would be required. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "comprises or consists of" is conflicting, thus it is confusing.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al. (US 6455066 B1).

Fischer et al. teaches a patch comprising a pressure sensitive adhesive comprising pharmaceutically acceptable salt and soybean oil (Claim 1), with aloe vera (Claim 2), backing is polyolefin, polyester, (Claim 4), polyolefin foil (Claim 5), with thickness of from about 0.6 mm to about 1.0 mm (Claim 6). Local anesthetic can be acetylsalicylic acid as an organic acid, buprenorphine and pharmaceutically acceptable salts thereof (column 5, lines 41-42, 44-46, 60-61). Penetration agents of N-methyl pyrrolidone (column 7, lines 9, 14). Preferred patches include matrix type patch (column 8, line 7). Preferably the adhesive is a synthetic rubber (column 8, lines 63-64). The adhesive may contain a crosslinker (column 9, lines 3-6).

The reference does teach that each of the claimed ingredients is suitable for combination in a pharmaceutical composition. Thus, an artisan of ordinary skill would be reasonably expected that the claimed ingredient could be combined together to produce a single pharmaceutical product. This reasonable expectation of success would motivate the artisan to combine the claimed ingredients together into a single composition.

Claims 1-6, 8, 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al. (US 6455066 B1) as applied to claims 1-6, 11-22 above, and further in view of Nielsen (US 6171594 B1).

Fischer et al. teaches a patch for skin comprising a pressure sensitive adhesive comprising pharmaceutically acceptable salt and soybean oil (Claim 1), with aloe vera (Claim 2), backing is polyolefin, polyester, (Claim 4), polyolefin foil (Claim 5), with thickness of from about 0.6 mm to about 1.0 mm (Claim 6). Local anesthetic can be acetylsalicylic acid as an organic acid, buprenorphine and pharmaceutically acceptable salts thereof (column 5, lines 41-42, 44-46, 60-61). Penetration agents of N-methyl pyrrolidone (column 7, lines 9, 14). Preferred patches include matrix type patch (column 8, line 7). Preferably the adhesive is a synthetic rubber (column 8, lines 63-64). The adhesive may contain a crosslinker (column 9, lines 3-6). However, it does not teach styrene-butadiene-styrene block copolymer.

Nielsen teaches adhesive agent for human or animal skin with styrene-butadiene-styrene copolymer (column 5, lines 37-38).

The references also do not specifically teach combining styrene-butadiene-styrene copolymer and rubber adhesives together. The reference does teach that these are adhesives used for skin (see discussion above). As discussed in MPEP 2144.06:

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third

composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.

Thus, it would be obvious to combine styrene-butadiene-styrene copolymer with other skin adhesives because they are taught in the reference to have the same purpose.

### ***Conclusion***

No claim is allowed.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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January 31, 2008